K101923

IX. 510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Eugene Bang Regulatory Affairs Associate Tel: 508-977-3966 Fax: 508-828-3797 Email: ebang@its.jnj.com
DATE PREPARED:	July 8, 2010
CLASSIFICATION NAME:	Intervertebral Body Fusion Device Spinal Intervertebral Body Fixation Orthosis
REGULATION NUMBER:	888.3060, 888.3080
PRODUCT CODE:	MAX, MQP
DEVICE CLASS:	Class II
PROPRIETARY NAME:	CONCORDE® Curve System
PREDICATE DEVICES:	LEOPARD® System (K081917) CONCORDE® Bullet System (K081917)
DEVICE DESCRIPTION:	CONCORDE® Curve System consists of cages of various sizes. This system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.
INTENDED USE:	The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet), TLIF (CONCORDE, CONCORDE

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Bullet, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation products.

MATERIALS:

The CONCORDE® Curve System is made from carbon-fiber reinforced polymer with tantalum wires.

TECHNOLOGICAL CHARACTERISTICS:

The purpose of this submission is to obtain market clearance for the proposed components to the CONCORDE® Curve System. The key difference between the subject and predicate devices is the addition of various sizes of the implants. These proposed components have the same design characteristics, performance, intended use, and packaging as the predicate devices.

PERFORMANCE DATA:

The testing of the CONCORDE® Curve System was performed in accordance with the following,

- Static and dynamic compression per ASTM F2077
- Static and dynamic compression shear per ASTM F2077
- Static and dynamic torsion per ASTM F2077
- Subsidence per ASTM F2267

The testing results demonstrated that CONCORDE® Curve implants performed as well as the predicate devices.

CONCLUSION: Based on the predicate comparison and testing, the subject device CONCORDE® Curve System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DePuy Spine, Inc.
% Mr. Eugene Bang
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02780

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Re: K101923
Trade/Device Name: CONCORDE® Curve System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: November 12, 2010
Received: November 15, 2010

Dear Mr. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. **Indications for Use**

510(k) Number (if known): K101923

Device Name: CONCORDE® Curve System

Indications For Use:

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The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation products.

Prescription Use ___X___	AND/OR	Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101923